

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF MARYLAND

FILE UNDER SEAL

UNITED STATES OF AMERICA )  
                                )  
                                )  
v.                            )     No. 10-cr-692-RWT  
                                )  
LAUREN STEVENS,           )  
                                )  
Defendant.                  )  
                                )

DECLARATION OF BRIEN T. O'CONNOR

I, Brien T. O'Connor, hereby declare and state as follows:

1. My name is Brien T. O'Connor. I offer this declaration in connection with motions to be filed by Defendant Lauren Stevens on December 17, 2010.
2. Except as otherwise noted, the information in this declaration relating to GlaxoSmithKline's ("GSK") response to the October 9, 2002 letter from the United States Food & Drug Administration ("FDA") is based on my review of the documents and materials made available to me as counsel to Ms. Stevens in this case, and not on firsthand knowledge or on any privileged communication.

Background

3. I am a partner in the law firm of Ropes & Gray LLP.
4. In or about June 2007, Ms. Stevens retained Ropes & Gray to represent her with regard to the government's investigation of GSK's response to the October 9, 2002 letter from FDA. Since June 2007, I led the firm's team which serves as counsel for Ms. Stevens.

**October 9, 2002 Letter from DDMAC to GSK**

5. On or about October 9, 2002, GSK received from FDA's Division of Drug Marketing, Advertising, and Communications ("DDMAC") an informal request for information (the "October 9 letter request").

6. The October 9 letter request stated that DDMAC possessed information that GSK "may be promoting the off-label use" of a GSK product known as Wellbutrin SR ("Wellbutrin") "for weight loss." Wellbutrin is an anti-depressant. Its FDA-approved label specifically refers to the "weight-reducing potential" of Wellbutrin as a recognized reason for considering whether to take Wellbutrin in certain circumstances. According to FDA-approved label (Precautions section) in 2003:

In studies conducted with the immediate-release formulation of bupropion, 35% of patients receiving tricyclic antidepressants gained weight, compared to 9% of patients treated with the immediate-release formulation of bupropion. If weight loss is a major presenting sign of a patient's depressive illness, the anorectic and/or weight-reducing potential of Wellbutrin SR Tablets should be considered.

7. The letter request was not a formal subpoena. Rather, it was a regulatory inquiry requesting that GSK voluntarily provide information. The October 9 letter request does not include any recitation of authority suggesting that GSK was legally required to respond.

8. Defendant Lauren Stevens, former GSK Vice President and Associate General Counsel, was the GSK in-house lawyer with primary responsibility for GSK's responses to the October 9 letter request. GSK lawyers Doug Snyder and Sherrie Shade, among others, also worked on this project. Both Mr. Snyder and Ms. Shade worked at FDA before working for GSK. Ms. Shade was the Wellbutrin product attorney and a former Regional Review Officer at FDA. Mr. Snyder, before joining GSK, had been Associate General Counsel at FDA for five years.

**The Role of King & Spalding**

9. On October 17, 2002, GSK retained King & Spalding LLP to provide assistance with the company's response to the October 9 letter request.

10. The three-person King & Spalding team was led by Mark Brown, a partner at King & Spalding with extensive FDA experience who specializes in matters concerning the FDA. Mr. Brown was a former Associate Chief Counsel at FDA. During his tenure at FDA, Mr. Brown had become one of the agency's chief litigators handling both civil and criminal pharmaceutical cases. Mark Jensen and Nikki Reeves, associates of King & Spalding during 2002 and 2003, assisted Mr. Brown.

11. In general terms, GSK retained King & Spalding to assist with responding to certain aspects of DDMAC's October 9 letter request. GSK and King & Spalding worked together in the drafting of the letters to FDA, with King & Spalding producing the first drafts of almost all the response letters before they were circulated to the other team members. King & Spalding reviewed multiple drafts of every letter sent to FDA. The firm also advised GSK with respect to the strategy for interacting with FDA.

**Review Performed by King & Spalding**

12. As stated in the opening paragraph of the October 9 letter request, the DDMAC inquiry was focused on the allegation that "GSK may be promoting the off-label use of Wellbutrin SR for weight loss." In the October 9 letter request, DDMAC also stated that "[a]mong the items in question are presentations by Dr. Donna Ryan, Dr. Owen Wolkowitz and Dr. James W. Anderson, and 'Speaker Training Slides for Wellbutrin SR' dated December 2001."

13. To prepare to respond to FDA's inquiry, GSK and King & Spalding conducted a review of documents and other materials in an effort to determine whether GSK was promoting the off-label use of Wellbutrin for weight loss. Mark Brown and Mark Jensen of King & Spalding also conducted over a dozen interviews of key GSK employees involved in the sales and promotion of Wellbutrin as part of that effort. The team also interviewed the three doctors of interest to the FDA, as identified specifically in the October 9 FDA inquiry, and evaluated speaker training slides identified in the letter and the distribution of those slides. King & Spalding concluded, on the basis of its review, that GSK had no corporate strategy to promote Wellbutrin to achieve weight loss or to treat obesity.

**GSK's Response to FDA's October 9 Letter**

14. The legal team sent six substantive letters of response to FDA between December 2002 and November 2003. The letters addressed FDA's major areas of inquiry and described, in narrative format, GSK's promotional program for Wellbutrin. The letters also disclosed several compliance problems with the marketing of Wellbutrin in violation of corporate policies that GSK and King & Spalding discovered during the course of their work in responding to the October 9 letter request. Each of these letters at issue in Counts Three through Six of the Indictment was drafted, edited and reviewed by King & Spalding. Draft copies of the letters were retained.

15. GSK and King & Spalding worked together in the drafting of the letters to FDA. King & Spalding produced the first drafts of almost all the response letters. King & Spalding also reviewed and provided comments on multiple drafts of every letter sent to FDA.

**The Indictment in this Case**

16. The next section of my declaration addresses certain allegations that appear in the Indictment in this case dated November 8, 2010 regarding false statements or concealment of material information allegedly made or found in GSK's written responses to the October 9 letter request.

**The Statements in GSK's February 28, 2003 Letter**

17. The Indictment addresses the February 28, 2003 letter at paragraphs 28 through 31 of the Introductory Allegations (pp. 7-8) and in Count Three (pp. 13-14). The Indictment charges that the following statements (among others) were knowingly false at the time they were made:

- a. GSK has not developed, devised, established or maintained any program or activity to promote or encourage, either directly or indirectly, the use of Wellbutrin SR as a means to achieve weight loss or treat obesity. . . . GSK's promotional material and activities for Wellbutrin SR are consistent with the approved Prescribing Information and supporting clinical data.
- b. GSK has not developed or maintained promotional plans or activities to directly or indirectly promote Wellbutrin SR for weight loss or the treatment of obesity.

18. King & Spalding prepared the first draft of the February 28, 2003 letter, based on the review that they conducted (generally described in ¶ 13 above) and the information GSK supplied, including regular conference calls with GSK lawyers. These statements were made based on the core conclusion of the responding team: that while GSK had encountered some noncompliant physician speakers, GSK itself had no centralized corporate strategy to promote Wellbutrin off-label to treat obesity. By these statements, King & Spalding and GSK intended the draft letter to reflect the opinion that GSK did not have a corporate strategy or program to promote Wellbutrin SR off-label for weight loss or for the treatment of obesity.

**Presentations Received from Physician Speakers**

19. The Indictment also appears to charge that GSK or Ms. Stevens acted illegally in not producing to FDA the presentations it received from physician speakers.

20. During a telephone conference on October 25, 2002, GSK told a representative of FDA that the Company would make a good faith effort to obtain from doctors under contract with GSK, and to provide to DDMAC, materials presented by physician speakers at GSK-sponsored promotional programs.

21. On or about December 12, 2002, GSK sent letters to over 500 physicians who had spoken for GSK during the relevant time period requesting copies of their presentations.

22. GSK received responses from only approximately 40 physicians. GSK forwarded all the materials it received from its speakers to King & Spalding. The team (including King & Spalding) reviewed each of the presentations and determined whether any of the slides were potentially off-label. The team determined that some of the slides did contain potentially off-label content. They also determined that, from the presentations alone and without interviewing the particular physicians who had those slide decks, they were unable to conclude if the presentations had been used and what the physicians actually said at their presentations, and therefore whether any speaker engaged in inappropriate promotion.

23. The GSK and King & Spalding team jointly considered whether to produce the presentations to FDA without providing the necessary context. At no time did King & Spalding advise or express a belief to GSK that the failure to produce the presentations was unlawful. GSK, consistent with its discussions with King & Spalding, decided not to produce the presentations to FDA with its May 2003 letter. Documents reflect that the team decided that instead of simply mailing the presentations, GSK would seek a meeting with FDA, at which the

presentations could be discussed.

24. King & Spalding advised GSK to seek a meeting with DDMAC to discuss, among other items, these presentations. At this meeting, the team expected that the presentations would be among the specific issues discussed, and that this meeting would provide GSK with an opportunity to explain the importance of conducting further review to learn more about the manner in which the slides were actually used by the physicians during their presentations, if at all. Ms. Stevens called FDA several times in May/June 2003 to schedule such a meeting. FDA, however, did not respond to Ms. Stevens' requests for a meeting.

25. The presentations were produced later in connection with a larger Department of Justice investigation (focused on multiple products and issues, not just marketing of Wellbutrin) that began in 2004.

**The Government Investigation**

26. Ms. Stevens was initially interviewed by the government in 2008. On May 5, 2009, the government sent a "target" letter to Ms. Stevens that indicated that if an indictment was issued, the venue would be Greenbelt, Maryland. The government sought and received a return of the Indictment now at issue in Greenbelt, Maryland on November 8, 2010.

I declare under the penalty of perjury that the foregoing is true and correct.

Executed on December 17, 2010.



Brian T. O'Connor